UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419
	)	Dkt. No. 1:13-md-2419-RWZ
This Document Relates to Suits Naming:	)	
Saint Thomas Outpatient Neurosurgical Center, LLC	)	

STOPNC DEFENDANTS' SUR-REPLY REGARDING THE PARTIES' CROSS-MOTIONS FOR PARTIAL SUMMARY JUDGMENT ON THE PLAINTIFFS' PRODUCT LIABILITY CLAIMS

MDL Order No. 11[1] permits sur-replies for dispositive motions. Pursuant to that order, Saint Thomas Outpatient Neurosurgical Center, LLC ("STOPNC"); Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; and Vaughan Allen, MD, file this Sur-Reply addressing specific arguments raised by the PSC related to the parties' Cross-Motions for Summary Judgment at Docs 2300 and 2462.

[1] Doc. 1524.

Introduction

The PSC asks the Court to find that the Plaintiffs' unprecedented claim for strict liability in tort for the delivery of health care services has always been a part of Tennessee law, a claim made without citation to a single appellate or trial court opinion validating the argument. There is no support in Tennessee's decisional law for the Plaintiffs' broad reading of Tennessee's Product Liability Act ("TPLA"), or for the Plaintiffs' narrow reading of Tennessee's Health Care Liability Act ("THCLA").

The undisputed facts and cases cited by the Defendants force the PSC to resort to a strained reading of the applicable statutes, and to disregard the holdings of *Ellithorpe*[2] and *Burris*.[3] While the PSC may ignore the plain language of the THCLA and the holdings of these cases, the Court cannot.

The only conclusion to be drawn from the undisputed facts and the applicable law is that STOPNC is not "engaged in the business of selling" MPA. Thus, no strict liability exists. Likewise, the Plaintiffs cannot escape the fact that their claims are "related to" the provision of health care services, necessitating application of the THCLA. Traveling down either path, summary judgment awaits the Plaintiffs' claims for strict product liability.

Law and Argument

The PSC's Reply at Doc. 2508 raised only a handful of arguments in opposition to the Defendants' position and left a number of points from the Defendants' briefing untouched.[4] This brief will address just those arguments raised at Doc. 2508.

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[2] *Ellithorpe v. Weismark*, --- S.W.3d ----, 2015 WL 5853873 (Tenn. Oct. 8, 2015).
[3] *Burris v. Hospital Corporation of America, Inc.*, 773 S.W. 2d 932 (Tenn. App. 1989).
[4] *See* pages 22-30 of the Defendants' Memo of Law at Doc. 2463, which were largely unaddressed by the PSC.

I. The Plaintiffs offer nothing upon which a reasonable juror could conclude that STOPNC was engaged in the business of selling a product except the *non sequitur* that charging a global fee for services establishes that STOPNC is a seller.

To establish a claim for strict liability, the Plaintiffs must do more than just allege a sale occurred. The burden falls on the Plaintiff to prove that the defendant (here, a health care provider) is "engaged in the business of selling a product."

A single sum payment to an ambulatory surgery center for services that include the use of products *does not* establish that the health care facility is "engaged in the business of selling" products. The PSC offers nothing to establish that indispensable element, and notably no legal authority supporting the concept that receipt of payment in return for a medical service – even if the service includes tangible products as part of the service – establishes STOPNC as a "seller" under the TPLA.

It is undisputed that STOPNC provided a series of services to the Plaintiffs during their epidural steroid injection procedures, in addition to the steroid, and that STOPNC was paid a single, global fee for the services and supplies it provided.[5] This undisputed fact does not permit the conclusion that STOPNC was *engaged in the business of selling a product.*[6] No regulation, statute, or case even suggests that the existence of a global fee somehow converts STOPNC into a grocery store or Wal-Mart engaged in the business of selling a product. The undisputed facts establish the opposite. STOPNC's business, at its core, is providing health care services to treat its patients' pain, *not* to sell medicine.

[5] STOPNC Defendants' SUMF at ¶ 12.

[6] Consider this illustration, which demonstrates the absurdity of the PSC's position: The PSC contends that payment of this global fee somehow establishes that a sale occurred. However, the cost of *supplies* used during the procedure is also included as part of the global fee that the PSC says establishes a sale. 42 CFR § 416.164(a)(5). But, no one could seriously claim that STOPNC was "engaged in the business of selling" latex gloves, even though money changed hands, in part, for the gloves used during the procedure.

II. The Plaintiffs offer nothing to rebut the reasonable and logical application of the predominant purpose test, which Tennessee has followed for years.

The Defendants have proposed using a test that is well-established in Tennessee law, the "predominant purpose test," to assist the Court in determining the applicable law. Although the predominant purpose test is most often applied to determine whether Article 2 of the UCC or common law principles govern a dispute arising from the delivery of both products and services, there is neither a legal nor logical reason to discount application of that test in these circumstances.

Application of the predominant purpose test irrefutably establishes that Article 2 has no application here because the transaction was not a "sale" of a good. Concerned not at all by logic or semantic consistency, the PSC urges the Court to find that there was a *sale* for the Plaintiffs' TPLA claims, while effectively conceding that the Plaintiffs' breach of warranty claims are meritless because there was *no sale* under the UCC.[7]

This curious, inconsistent position is supposedly dictated by the holding in *Baker v. Promark Prods. W., Inc.*[8] The PSC implies that the Tennessee Supreme Court considered the interaction between the TPLA and UCC in *Baker*, and found them to be distinct and unrelated statutory schemes. That position is off the mark.

Baker (dealing with an injury caused by a leased stump grinder) recognized that a lessor or bailor could be a seller under the TPLA, but not the UCC.[9] The court in *Baker*, however, specifically stated that the holding was based on the following statutory language of the TPLA: "Seller shall also include *a lessor or bailor engaged in the*

[7] The Plaintiffs also assert claims for breach of warranty under Article 2 of the UCC. 2nd Am. Master Compl. ¶ 324 [Doc. 1719].
[8] 692 S.W.2d 844 (Tenn. 1985).
[9] *Id.* at 847.

business of leasing or bailment of a product."[10] The Tennessee Supreme Court also stated in *Baker* that provisions of the UCC and TPLA "must be read in conjunction."[11] *Baker* offers nothing to the analysis here.

The Court would be better served to look to the multiple courts, including the Sixth Circuit, that have held that an amendment to Tennessee's codification of the UCC also amended by implication the TPLA, immunizing health care providers from any form of strict liability for transfusions or blood, implantation of human tissue, bones or organs, and injection of any form of blood derivatives.[12] These opinions demonstrate that Tennessee courts recognize that "[b]oth claims in strict liability and in breach of warranty are grounded in the concept of a sale of a product."[13] As such, Tennessee's test for the applicability of the UCC is relevant here in the context of a supposed product liability claim to determine if a "sale" occurred.

It is entirely consistent with Tennessee law, and appropriate, for the Court to look to cases interpreting the UCC for guidance on interpreting whether a sale occurred under the TPLA. Applying those decisions – and the predominant purpose test – the Court must find that STOPNC was not "selling" MPA to patients when it was administered as part of a medical procedure.

III. There is a conflict between the TPLA and the THCLA; under case law and canons of statutory construction, the THCLA should apply.

The Plaintiffs simultaneously claim that the TPLA must be construed broadly to capture their claims, but narrowly to avoid conflict with the THCLA. The opening

[10] *Id.* (emphasis added) ("We base our conclusion that chattel leases are included within the Products Liability Act on the specific language and legislative history of the Act.").
[11] *Id.*
[12] *See McDaniel v. Baptist Memorial Hosp.*, 352 F. Supp. 690, 691 (W.D. Tenn. 1971) *aff'd* 469 F.2d 230, 234 (6th Cir. 1972); *Sawyer v. Methodist Hosp. of Memphis*, 383 F. Supp. 563, 568 (W.D. Tenn. 1974); *St. Martin v. Doty*, 493 S.W.2d 95, 97 (Tenn. App. 1972).
[13] *Sawyer*, 383 F. Supp. at 568.

language defining the scope of each Act establishes an unavoidable conflict. The TPLA applies to "all actions brought for…personal injury…caused by or resulting from…[a defective product]…under any…substantive theory in tort or contract whatsoever."[14] The THCLA applies to all claims "related to…the provision of health care services… regardless of the theory of liability on which the action is based."[15]

There is a critical difference between the two statutes: the THCLA does *not* say "caused by" the provision of health care services; it says "*related to*," an important distinction here. Even if the Plaintiffs' TPLA claims do not allege injuries *caused by* the health care services (although they do), they clearly allege injuries *related to* the health care services. This invokes the THCLA, creating a conflict between the two statutes.[16]

The Plaintiffs' injuries all arise from their epidural steroid injection procedure. The latent defect in the vials of methylprednisolone acetate ("MPA") sold by NECC did not cause injury in the vials' inert state. The injury occurred only as a result of the use of that product during the course of epidural steroid injections. Without the health care services, there would be no injury, and no claim.

The holding in *Ellithorpe* (recognizing the THCLA's broad application) and well-settled canons of statutory construction require the Court to apply the THCLA, the more recent statute.

IV. *Graves v. Qualitest Pharms.*[17] is not even persuasive on any relevant point.

The PSC urges the Court to look to *Graves v. Qualitest Pharms.* for guidance on the interaction between the TPLA and THCLA. However, the PSC omits critical points

[14] TENN. CODE ANN. § 29-28-102.
[15] TENN. CODE ANN. § 29-26-101.
[16] The Plaintiffs do not dispute in their Reply that a conflict exists if both statutes apply.
[17] No. 12–cv–01185–JDB–egb, 2013 WL 3198165 (W.D. Tenn. June 21, 2013).

from its discussion of *Graves*. First, the case considered an issue entirely unrelated to the case at bar – whether pharmacists have a post-sale duty to warn. Second, and tellingly, there is no mention of the THCLA anywhere in the *Graves* opinion. More importantly, the court in *Graves* could not even conclude whether Tennessee's comprehensive 2011 tort reform applied to the case.[18] So, the new, broad THCLA, applicable here, may not have even applied at the time of the events in *Graves*.

Not only does *Graves*, an unreported district court case decided under the fraudulent joinder standard,[19] have no precedential value, it does not even involve both statutes at issue. The PSC's reliance on *Graves* is sorely misplaced, and the Court would be well-served to decline the PSC's invitation to make the same error.

V. The Court cannot disregard *Burris.*[20]

Next, the PSC urges the Court to disregard the only Tennessee appellate opinion that squarely addresses the issue before the Court, *Burris v. Hospital Corporation of America, Inc.* The PSC boldly (mis)states in its brief:

> Nowhere in the decision does it appear that the plaintiff asserted a claim that the medical device at issue was unreasonably dangerous or that the device itself caused the injury. Rather the inquiry appeared to be whether the doctor prudently chose to leave the medical device in the patient.[21]

This statement is simply false. The Tennessee Court of Appeals explicitly stated in the opinion, "Plaintiff asserts that this suit against appellee involves the

[18] The court in *Graves* was interpreting a provision of the TPLA that was amended by the 2011 tort reform and did not reach a conclusion as to which version of the statute applied. *Id.* at *2. The 2011 amendments to the TPLA did not affect the definition of "seller" at issue here.

[19] As the Court knows, examining the complaint for the purposes of fraudulent joinder is an even more liberal standard than a motion to dismiss under Fed. R. Civ. P. 12(b)(6). *See Rosbeck v. Corin Group, PLC*, --- F.Supp.3d ----, 2015 WL 6472249 at *3 (D. Mass. Oct. 27, 2015) ("[O]ther jurisdictions (as far as the Court can tell) universally review claims of fraudulent joinder under a standard more lenient than that for a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6)." (internal citations and quotations omitted)).

[20] 773 S.W. 2d 932 (Tenn. App. 1989).

[21] Doc. 2508 at 12.

characteristics of a products liability case which is not comprehended within the [predecessor to the THCLA]."[22] The PSC's desperate attempt to distinguish *Burris* by mischaracterizing its reasoning may be the best indicator of its applicability here.

VI. The PSC's contention that the Defendants' positions lack candor misses the real points.

The PSC blithely (and inaccurately) accuses the Defendants of "lack of candor" with the Court on two points.[23]

First, the PSC claims that the Defendants misled the Court by pointing to the fact that STOPNC does not charge sales tax as evidence that STOPNC is not a seller. The Plaintiffs claim that the Defendants somehow hid the fact that STOPNC is exempted from sales tax by statute. The reverse is actually true. The Defendants cited directly to the applicable regulation in their memo of law at footnote 27. More importantly, the PSC's obsession with leveling unfounded accusations caused it to miss the point: The exemption *proves* the Tennessee legislature's recognition that, when a health care provider gives medication to a patient, *there is no sale to tax*.

Second, the Plaintiffs claim that the Defendants misrepresent the significance of the CMS definition of an ambulatory surgery center ("ASC"). The PSC asserts that the definition is merely meant to distinguish ASCs, which admit patients for less than 24 hours, from health care providers who see patients for different periods of time. According to the PSC, "All [the definition] means is that ASCs exclusively see patients for less than 24 hours following an admission."

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[22] *Burris*, 773 S.W. 2d at 935.

[23] This is particularly ironic given statements by the PSC to the Court at the December status conference. The PSC suggested to the Court that the health care liability statute of repose would operate to bar the refiling of recently nonsuited cases *Branham* and *Kinsey*. Tenn. Code Ann. § 28-1-105 explicitly permits the cases to be refiled within one year of the first nonsuit. It is well-settled under Tennessee law that the statute of repose does not operate to bar the cases from being refiled within a year of the nonsuit. *Sharp v. Richardson*, 937 SW 2d 846, 847 (Tenn. 1996); *Cronin v. Howe*, 906 SW 2d 910, 914-15 (Tenn. 1995).

The PSC misunderstands the statutory scheme. Yes, to qualify as an ASC the length of admission must be shorter than 24 hours. If the admission is longer than 24 hours, the facility is classified as an inpatient hospital. And, like ASCs, inpatient hospitals receive a single, global facility fee for the services provided during a patient's medical procedure. Again, like ASCs, the CMS regulations applicable to inpatient hospitals explicitly state that the reimbursement provided to inpatient hospitals as part of the facility fee is for *services*.[24] Yes, the definition addresses the length of the stay. But, this does not change the fact that CMS treats ASCs and hospitals as service providers, not sellers of goods.

It is manifestly clear that even Congress recognizes that the global facility fee paid to health care facilities is predominantly for *services*, even when products are incidentally provided.

VII. The silicone breast implant exception to the TPLA cannot be stretched to create a new cause of action for health care provider strict liability or be interpreted to establish a sale of medication during a medical service.

Finally, the PSC relies on an exception to an exception to the TPLA's statute of limitations, and claims this conclusively establishes legislative intent to treat each and every health care provider (save only those selling silicone breast implants) as "sellers" of medical products. The PSC makes the unfounded claim that no other portion of the Tennessee Code recognizes that health care providers are not sellers of products used in the delivery of medical services. Each assertion is categorically in error.

First, Tenn. Code Ann. § 47-2-316, an element of the law of Tennessee since *1967*, specifically states that the injections of blood products and blood derivatives, and transplantation of human tissues, corneas, bone, and other natural materials, are

[24] 42 CFR § 409.10 ("Included Services").

medical services, not sales. Thus, the claim that no other part of the Code recognizes that health care providers are not sellers is wrong.

Second, regardless of the misstatement, an amendment to the product liability statute of limitations does not magically make health care providers "sellers" of every product they use. The Constitution of Tennessee requires the subject of an act to be addressed in the title, and that "All acts which repeal, revive or amend former laws, shall recite in their caption, or otherwise, the title or substance of the law repealed, revived or amended."[25] If this statute actually operated as the PSC reads it – to make health care providers sellers of every product they use except silicone breast implants – the title of the bill would have been "an Act to make health care providers sellers of everything except breast implants." Instead, the title of the Act was "an Act to amend Tenn. Code Ann. § 29-28-103 relative to the statute of limitations."[26]

The Court should not read such broad legislative intent into a legislative modification of the product liability statute of limitations, where there is no suggestion in the title or the language that the legislature intended the provision to do anything other than modify the product liability statute of limitations. The clear *and only clear* purpose of the statute was to extend the statute of limitations against the manufacturers of breast implants.

Further, there is good reason to specifically exempt health care providers from liability for defective silicone breast implants. Breast implants (like all permanent, implantable medical devices) are ***not*** typically included as part of the global facility fee

[25] TENN. CONST., art. III., § 17.
[26] *See* also legislative history of silicone breast implant exception, provided with the Defendants' Reply in Support of their Motion to Dismiss at Doc. 1112.

charged for a procedure.[27] In other words, there is a *specific, separate charge* by the health care facility for the cost of the breast implants. That is simply not the case for the MPA administered to the Plaintiffs during their procedures.

Conclusion

At the oral argument on December 17, 2015, the PSC spent much of its time trying to link how Dr. Culclasure is paid (not a salary, but a percentage of revenue) and STOPNC's volume of work (it was busy) to its legal argument in support of a finding of strict product liability. Specious arguments like these are only intended to mask the gaping holes in the PSC's legal analysis.

At its best, the PSC's argument calls on support only from an exception to an exception to the product liability statute of limitations. A strained reading of a single provision in a 71-title codebook cannot outweigh the laundry list of relevant Tennessee opinions, persuasive opinions from outside Tennessee, statutes, regulations, and secondary sources, all of which support the Defendants' position that they cannot, as a matter of law, be held strictly liable in this setting. STOPNC was not, is not, and never will be engaged in the business of selling medication used incidental to health care services. It was, is, and will be a service provider, subject to liability under the THCLA.

[27] *See* Amendment to BCBS Contract at Doc. 2464-2 at 40 (Bates numbered STOPNC – 017967) (specifying amount of reimbursement for implants); 42 C.F.R. 419.66 (specifying criteria for separate payment for medical devices, including implants, for Medicare beneficiaries).

Respectfully submitted,

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CERTIFICATE OF SERVICE

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